EXHIBIT E

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REVIEW ARTICLE

Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis

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Abstract
Introduction and hypothesis Questions regarding the long-term efficacy and safety of midurethral slings (MUS) are still unresolved, notwithstanding the widespread use of these procedures. The objective of this review was to evaluate the long-term outcomes of retropubic MUS (RP-MUS) procedures and the medium-term outcomes of transobturator MUS (TO-MUS) procedures.
Methods MEDLINE, EMBASE, NLH, ClinicalTrials.gov, and Google Scholar databases were searched up to June 2014 with restriction to English language and using the search terms: "stress urinary incontinence", "midurethral sling", "tension-free tape", "transobturator tape", and "follow-up". Studies with a follow-up of 36 months for TO-MUS and 60 months for RP-MUS were searched. Only studies comparing a RP-MUS or TO-MUS with another synthetic sling were included. Data from 49 studies were included. Data were expressed as odds ratios (OR) with 95 % confidence intervals (CI) and combined using the Mantel-Haenszel fixed effects model. Differences in the proportions were evaluated using the chi-squared test.
Results RP-MUS had similar objective cure rates (OR 1.15, 95 % CI 0.75 – 1.76) but higher subjective cure rates than TO-MUS (OR 1.76, 95 % CI 1.08 – 2.86). No differences were observed between outside-in (TOT) and inside-out (TVT-O) and between TO-MUS and minisling. Bladder injuries were more frequent (OR 7.01, 95 % CI 2.94 – 17.90) and vaginal erosions were less frequent for RP-MUS (OR 0.24, 95 % CI 0.07 – 0.84). Vaginal injuries were more common with TOT than with TVT-O (OR 7.96, 95 % CI 1.15 – 157.9). Pain-related complications were more common with TO-MUS than with minimally invasive tapes (OR 8.75; 95 % CI 9.02 – 57.90).
Conclusions MUS have similar objective cure rates in the long term and medium term. TO-MUS is associated with a lower subjective cure rate than RP-MUS.

Keywords Long-term follow-up · Meta-analysis · ?Stress urinary incontinence · TOT · TVT

Introduction

Retropubic midurethral slings (RP-MUS) and transobturator midurethral slings (TO-MUS) (inside-out, TVT-O, and outside-in, TOT) are widely used procedures for the surgical treatment of female stress urinary incontinence (SUI), yielding high cure rates [1]. However, there are concerns about the safety of both approaches: RP-MUS have been related to bladder perforations and hemorrhagic complications, and TO-MUS seem to be linked to persistent and/or chronic groin/thigh pain [2]. Concerns about the safety and effectiveness of vaginal meshes led the FDA to

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release a notification on the subject of complications following their use (http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm). Even though the notification concluded that serious adverse events following the use of vaginal meshes for pelvic organ prolapse are not rare, slings were deemed to be relatively safe. Notwithstanding this document, MUS continue to be an issue, and some regulatory bodies are planning to limit their use until new evidence shows their safety (http://www.sehd.scot.nhs.uk/cmo/CMO(2014)15.pdf). Adding to the debate is the fact that their long-term efficacy has also been questioned by these same regulatory bodies.

A number of meta-analyses evaluating MUS have shown both their superiority in comparison with other techniques (colposuspension, autologous fascia slings, single-incision slings) and their efficacy and safety in different patient populations [1, 3–11]. All these meta-analyses included mainly short-term studies with only a few medium-term studies, and no long-term studies. In the case of prosthetic material, it has been suggested that only studies evaluating results 5 years after the original procedure can be defined long-term follow-up studies, with medium-term follow-up studies limited to those evaluating results 3 years after the original procedure [12].

The aim of this systematic review and meta-analysis of the literature was to evaluate the long-term effectiveness and safety of RP-MUS and the medium-term outcomes of TO-MUS procedures for SUI reported in randomized controlled trials (RCT) and nonrandomized studies and to compare those outcomes with those associated with different types of MUS.

Sources

An updated meta-analysis was performed following the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) Statement guidance [13]. All studies investigating the medium-term and long-term effectiveness and safety of MUS in women affected by SUI were included in this review. They were identified by searching the MEDLINE, EMBASE, National Library for Health, ClinicalTrials.gov, and Google Scholar databases (up to June 2014). The abstracts from International Conferences were not included in this systematic review. The search terms included simple text or subject subheadings with the language limited to English. They included: “stress urinary incontinence”, “midurethral sling”, “tension-free tape”, “transobturator tape”, and ”follow-up”. A hand search of the bibliographies and citation lists of all relevant reviews and primary studies was performed to identify articles not captured by the electronic searches with restriction to the English language. No ethical approval was requested because the study was a systematic review and meta-analysis.

Study selection

Retrospective, cohort, prospective nonrandomized studies and RCTs of women who had undergone RP-MUS or TO-MUS (including TVT-O and TOT) as the primary procedure for SUI with a mean or median follow-up of at least 36 months for TO-MUS and at least 60 months for RP-MUS were included. RCTs comparing RP-MUS and TO-MUS required a minimum follow-up of 36 months to be included in the analysis. No limitations concerning inclusion criteria of each study were set and only studies comparing RP-MUS or TO-MUS and another synthetic sling were included in this review. Studies including exclusively devices no longer available on the market at the date of the review were excluded. Studies including both RP-MUS or TO-MUS on the market and a device not on the market were included.

Three reviewers (G.A.T., C.F. and A.F.) selected the studies independently on the basis of the inclusion criteria and clarifications were sought from the individual trial lists if required. Disagreements among reviewers as to the studies to include were solved by discussion and, if necessary, by a majority decision of the reviewers. In cases of duplication, the study with the most recent data was included. In case of cohort studies with multiple publications, the last dataset on efficacy was used, while safety data were extracted from all published articles.

Three researchers (G.A.T., C.D.C. and C.F.) extracted data for quality and results independently. Data included the characteristics of patients (number, lost to follow-up and age), intervention, comparison for RCTs, follow-up length, exclusion criteria, preoperative and outcome assessment methodology, and results of the studies. The Jadad score was used to assess the quality of RCTs and the Newcastle-Ottawa scale was used for nonrandomized studies. The risk of bias across studies was assessed according to the Cochrane Handbook for Systematic Reviews.

Statistical analyses were performed by one author (G.A.T.). Statistical analyses of the RCTs were performed using RevMan 5.3 software (The Nordic Cochrane Center, Copenhagen, Denmark). For homogeneity, the per-protocol outcomes were used in the meta-analysis. For dichotomous data, the results of each study were expressed as odds ratios (OR) with 95 % confidence intervals (CI) and combined for meta-analysis using the Mantel-Haenszel method (fixed effects model). For nonrandomized studies, regression rates from individual studies were meta-analyzed using a fixed effects model. Statistical analyses were performed using CMA software (Biostat, Englewood, NJ). Heterogeneity among studies was analyzed using I^2. Differences in the proportions of complications were evaluated using the chi-squared test and are expressed as OR with 95 % CI. Statistical significance was set at $p<0.05$.

Results

A flow chart of the study selection process is shown in Fig. 1. We identified 78 potentially relevant studies and all underwent detailed review. Of these studies, 29 were excluded due to duplication of data reported in included studies, follow-up not meeting the inclusion criteria, outcome not reported or not completely specified, unclear study design, device not available on the market, or nonstandard device or procedure used. Thus, a total of 49 studies were included in the review.

There were 11 RCTs [14–24] and 38 nonrandomized studies, including prospective, retrospective, and cohort studies [25–62] with a total of 6,406 patients (1,200 in RCTs and 5, 206 in nonrandomized studies) aged 19 – 89 years. The sample size ranged from 15 to 563 patients evaluated at the last follow-up. The characteristics of the included studies are shown in Tables 1 and 2. The total numbers of patients evaluated according to the device used are shown in Table 3.

All RCTs showed a Jadad score of ≥3, with the exception of two studies [20, 24] (Table in Electronic supplementary material). A power calculation was reported in six studies (54.5 %). Among the non-RCT studies, SUI was clinically diagnosed in eight (no urodynamic studies performed) [26, 34, 36, 41, 48, 51, 53, 60] and a blinded assessment was performed in only three [40, 50, 51] (Figure in Electronic supplementary material). Outcome was assessed as a composite measure of cure (objective and subjective definition of cure met) [20, 24, 30, 31, 35, 59], subjective [14, 19, 21, 26, 34, 36, 38, 39, 42, 44, 48], objective outcome [15, 16, 22, 50] or both [17, 18, 23, 25, 27–29, 32, 33, 37, 40, 41, 43, 45–47, 49, 51–58, 60–62]. The follow-up was described in each study with a minimum of 36 months and a maximum of 17 years. Subjective parameters and objective outcome measures used in the studies included are reported in Electronic supplementary material.

Cure and success rates

On meta-analysis of RCTs, the ORs for objective cure with RP-MUS and TO-MUS were similar (OR 1.15, 95 % CI 0.75 – 1.76; p=0.72; Fig. 2a). The two different transobturator approaches were not significantly different from RP-MUS. The subjective cure rate with RP-MUS was significantly higher than with TO-MUS (OR 1.76, 95 % CI 1.08 – 2.86; p=0.02; Fig. 2b). Separate analysis of TVT-O and TOT showed that subjective cure rate with TOT was lower than with RP-MUS (OR 3.80, 95 % CI 1.74 – 8.33; p=0.0008), while there was no difference between RP-MUS and TVT-O but based on only one study [16] (OR 0.92, 95 % CI 0.47 – 1.80; p=0.81; Fig. 2b).

There were no RCTs comparing TVT-O with TOT in which objective outcomes were reported, while a single study [14] showed similar odds of subjective cure (OR 1.08, 95 % CI 0.61 – 1.91; p=0.80). Similarly, the only RCT comparing the composite cure rates of TVT-O and TOT [20] showed similar outcomes (OR 0.92, 95 % CI 0.25 – 3.32; p=0.80). Objective and subjective cure rates in RCTs were similar when comparing TO-MUS and Tissue Fixation System (TFS), TVT SECUR and TVT ABBREVO (objective cure OR 1.06, 95 % CI 0.59 – 1.91; subjective cure OR 1.26, 95 % CI 0.68 – 2.33; Fig. 3).

Considering the non-RCTs, RP-MUS showed cumulative subjective, objective and composite cure rates of 72.7 % (95 % CI 70.9 – 74.5 %), 83.2 % (95 % CI 80.8 – 88.7 %), and 84.1 % (95 % CI 81.7 – 86.1 %), respectively (Fig. 4).TO-

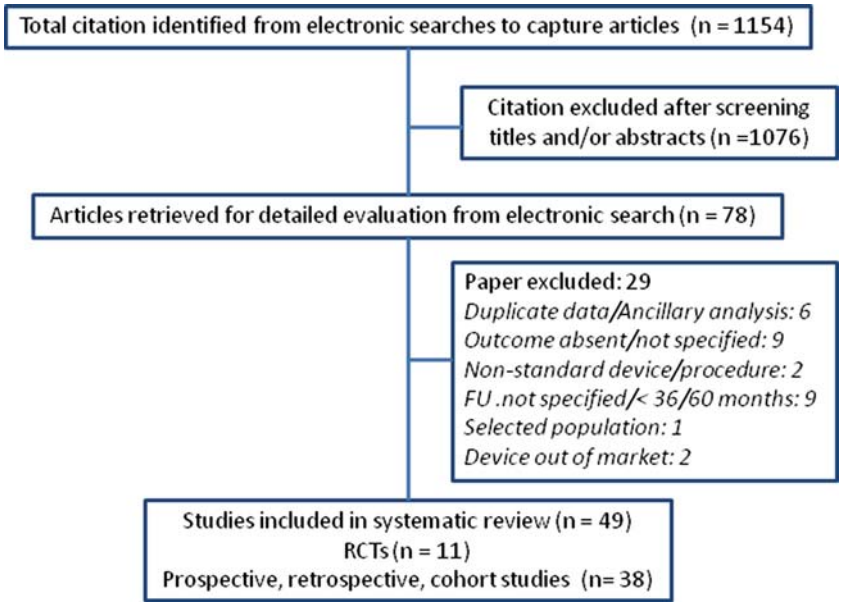


Fig. 1 Selection process for the systematic review

Table 1 RCTs included in the systematic review

Study	Intervention	Comparator	No. of patients		Follow-up duration	Lost to FU	Urodynamic studies	Objective cure	Subjective cure	Composite cure	Validated questionnaire
			Intervention	Comparator							
[14]	TVT-O	TOT Aris	170	171	60 months	44/59	X		X		X
[15]	TVT	TVT-O	35	37	5 years	6/6	X	X			
[16]	Retropubic I-Stop	TOT I-Stop	42	46	52.7/53.1 months	8/9		X			X
[17]	TVT	Obtape	73	75	100 months	33/28	X	X	X		X
[18]	TVT	TVT-O	136	132	60 months	5/9		X	X		X
[19]	TVT	Monarc	50	50	46 months	3/4			X		X
[20]	TVT-O	Monarc	39	35	3 years	–	X			X	
[21]	TVT	TOT	82	82	3 years	10/7	X		X		
[22]	TOT I-Stop	TFS	40	40	60 months	4/4	X	X			
[23]	TVT-O	TVT SECUR	77	77	36 months	11/13	X	X	X		X
[24]	TVT-O	TVT ABBREVO	87	88	36 months	13/9	X	X		X	X

TVT-O, *TVT*, *TVT SECUR*, *TVT ABBREVO*: Ethicon Gynecare, Cincinnati, OH

Aris: Coloplast, Minneapolis, MN

I-Stop: CL Medical, Winchester, MA

Obtape: Mentor, Minneapolis, MN

Monarc: AMS, Minnetonka, MN

TFS: TFS Surgical, Adelaide, Australia

Table 2 Prospective, retrospective and cohort studies included in the systematic review

Study	Intervention	Comparator	No. of patients		Follow-up duration	Lost to FU	Urodynamic studies	Objective cure	Subjective cure	Composite cure	Validated questionnaires
			Intervention	Comparator							
[25]	TVT	–	210	–	115.7 months	69		X	X		X
[26]	TVT	–	707	–	5 years	436			X		
[27]	TVT-O	–	145	–	90.3 months	21	X	X	X		X
[28]	TVT	–	158	–	5 years	57	X	X	X		X
[29]	Monarc	Obtape	26	37	5 years	30	X	X	X		X
[30]	TVT	–	600	–	63.1 months	37	X	X	X		
[31]	TVT	–	64	–	5 years	12	X			X	X
[32]	TVT-O	–	103	–	65 months	3		X	X		X
[33]	TVT-O	Monarc	89	124	58.2/59.9 months	2/7	X	X	X		
[34]	TVT	–	61	–	83 months	20			X		
[35]	TVT	–	155	–	67 months	17	X			X	
[36]	TVT	–	173	–	5 years	158			X		X
[37]	TVT	–	50	–	67 months	67		X	X		
[38]	TVT	–	60	–	10 years	8	X		X		
[39]	TVT	–	113	–	12 years	32	X		X		X
[40]	SPARC	–	86	–	5.2 years	40	X	X	X		
[41]	Monarc	–	191	–	6.5 years	52		X	X		X
[42]	TVT-O	Monarc	93	98	38/39 months	18/12	X		X		
[43]	TVT	–	161	–	6 years	32	X	X	X		
[44]	TVT	–	275	–	85.5 years	134	X		X		X
[45]	TVT	–	55	–	81.8 months	–	X	X			X
[46]	TVT	–	70	–	7 years	9	X	X	X		
[47]	TVT-O	–	121	–	4 years	6	X	X	X		
[48]	TVT	–	40	–	5 years	10			X		X
[49]	SPARC	–	151	–	7.6 years	58	X	X			
[50]	TVT-O	TVT SECUR	73	79	3 years	6		X			X
[51]	TVT	–	90	–	201 months	32		X	X		X
[52]	TVT	–	124	–	5 years	28	X	X	X		X
[53]	TVT	–	147	–	138 months	32		X	X		
[54]	TVT	IVS	103	213	78/56 months	25/52	X	X	X		
[55]	TVT/-O	–	422	–	36	237	X	X	X		
[56]	TVT	–	157	–	102 months	17	X	X	X		X
[57]	TVT	–	63	–	10 years	5	X	X	X		

Table 2 (continued)

Study	Intervention	Comparator	No. of patients		Follow-up duration	Lost to FU	Urodynamic studies	Objective cure	Subjective cure	Composite cure	Validated questionnaires
			Intervention	Comparator							
[58]	TVT-O	–	191	–	60 months	6	X	X	X		X
[59]	TVT	–	364	–	7 years	58	X			X	
[60]	TVT	–	542	–	129 months	59		X	X		X
[61]	TVT-O	–	102	–	40 months	11	X	X	X		X
[62]	TVT	TOT	100	108	48 months	–	X	X	X		X

TVT-O, *TVT*, *TVT SECUR*: Ethicon Gynecare, Somerville, NJ

Obtape: Mentor, Minneapolis, MN

Monarc, *SPARC*: AMS, Minnetonka, MN

IVS: Tyco-Covidien

MUS showed cumulative subjective and objective cure rates of 82.1 % (95 % CI 79.9 – 84 %) and 83.5 % (95 % CI 81.1 – 85.7 %; Fig. 5).

Complications

Overall, there were 766 complications reported with RP-MUS (complication rate 19.3 %; 72 in RCTs, 20.4 %. and 694 in non-RCTs, 19.2 %) and 579 with TO-MUS (complication rate 23.8 %; 198 in RCTs, 23.4 %, and 381 in non-RCTs, 24.0 %). De novo overactive bladder (OAB) symptoms (10 %) and urinary tract infections (UTI, 9.3 %) were the most common complications of RP-MUS, while de novo OAB symptoms (10.3 %) and postoperative and chronic pain (5.9 %) were the most frequent complications of TO-MUS (Fig. 6). Not all studies clearly defined postoperative, persistent and chronic pain. Defining as persistent pain all pain reported beyond the perioperative period (>7 days after procedure), no differences were observed between RP-MUS and TO-MUS (2.2 % vs. 1.9 %). UTIs (10.1 % vs. 3.6 %, OR 3.29, 95 % CI 2.07 – 5.28; $p<0.001$), and bladder/urethral perforations (2.5 % vs. 0.4 %, OR 7.01, 95 % CI 2.94 – 17.90; $p<0.001$) were more common with RP-MUS than with TO-MUS, while vaginal injuries (3.3 % vs. 0.4 %, OR 7.96, 95 % CI 1.15 – 157.9; $p=0.02$) and pain (5.9 % vs. 1.8 %, OR 3.47, 95 % CI 1.93 – 6.35; $p<0.001$) were more frequent with TO-MUS.

In RCTs comparing RP-MUS and TO-MUS, 72 (17.2 %) and 77 (18.2 %) complications were reported, respectively. This outcome was not significantly different between the

Table 3 Number of patients treated and evaluated in the medium-term and long-term per type of device

	Device	All studies	RCTs	Non-RCTs
Retropubic	TVT	3,801	319	3,482
	I-Stop	34	34	–
	SPARC	139	–	139
Total retropubic		3,974	353	3,621
Transobturator	TVT-O	1,375	459	916
	Monarc	449	81	368
	Aris	112	112	–
	TOT	178	75	103
	I-Stop TOT	73	73	–
	IVS	161	–	161
	Obtape	84	47	37
Total transobturator		2,432	847	1,585
Mini-invasive devices	TFS	36	36	–
	TVT SECUR	141	64	77
	TVT ABBREVO	79	79	–
Total mini-invasive devices		256	179	77

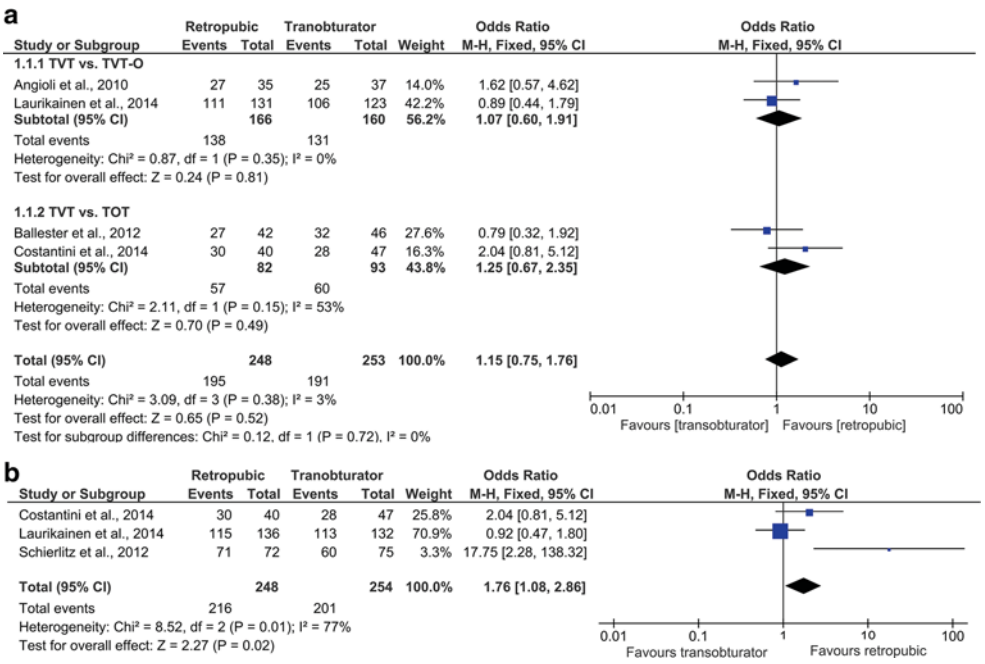


Fig. 2 Meta-analysis of the efficacy of retropubic and transobturator TVT (RCTs). **a** Objective cure rates; **b** Subjective cure rates

two approaches (OR 0.94, 95 % CI 0.68 – 1.29; p=0.68; Fig. 7a–b). Bladder injuries were more frequent with RP-MUS (OR 6.80, 95 % CI 1.77 – 26.07; p=0.005) than with TO-MUS. Pain was not different between RP-MUS and TO-MUS (OR 0.78, 95 % CI 0.19 – 3.20).No significant difference was observed in complication rates between TVT-O and TOT (OR 0.80, 95 % CI 0.52 – 1.21; Fig. 7c). Vaginal injuries were more common with TOT than with TVT-O (OR 0.16, 95 % CI 0.05 – 0.57). Complications were more common with TO-MUS than with the newer minimally invasive tapes (OR 1.99, 95 % CI 1.05 – 3.75; p=0.03; Fig. 7d). This result was due exclusively to pain-related complications, which were more common with TO-MUS (OR 8.75, 95 % CI 2.02 – 37.90; p=0.004), based on three studies [21–23]. Excluding this type of complication, no significant differences were observed (OR 0.99, 95 % CI 0.45 – 2.19; p=0.98).

Tape-related long-term complications

Overall, vaginal erosions were not different between RP-MUS and TO-MUS (Fig. 6), being 2.1 and 2.7 %, respectively. Persistent or chronic pain (i.e. pain persisting beyond the perioperative period or reported at the last follow-up visit) was reported by 13 patients for RP-MUS and 30 patients for TO-MUS. Persistent or severe voiding problems (defined either by difficulties persisting beyond the perioperative period or needing a tape release) were observed in 55 patients for RP-MUS and 39 patients for TO-MUS.

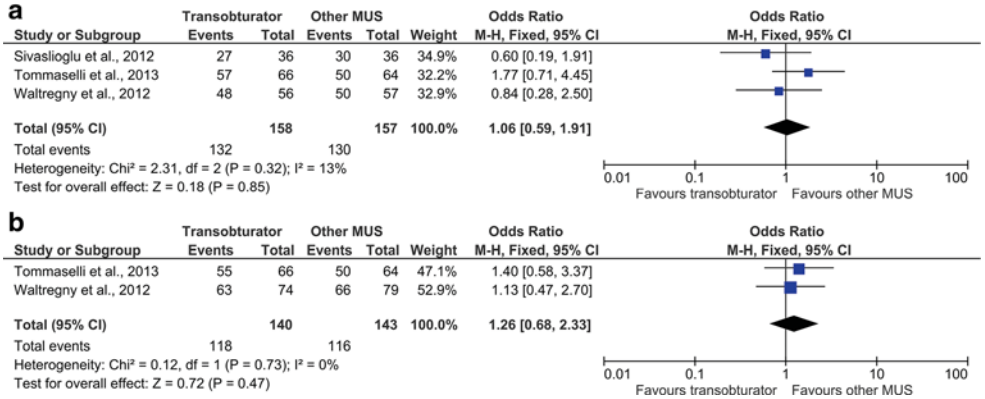
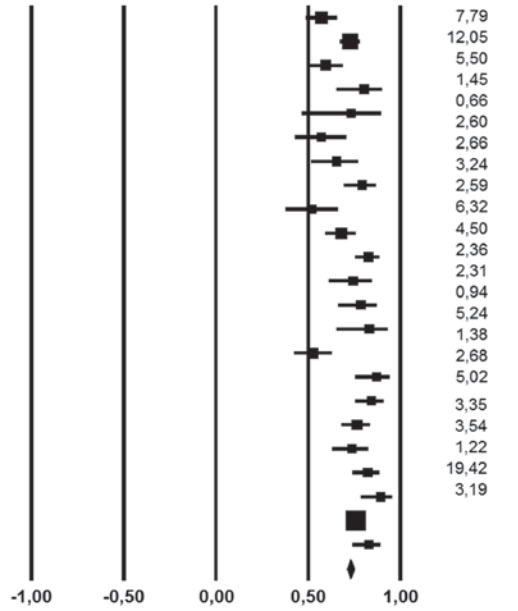


Fig. 3 Meta-analysis of the efficacy of transobturator tapes and TFS, TVT SECUR, and TVT ABBREVO (RCTs). **a** Objective cure rates; **b** Subjective cure rates

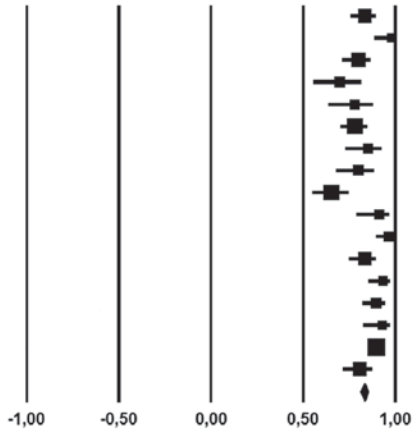
a

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Aigmueller et al., 2011	0,574	0,492	0,653	1,762	0,078	7,79
Ankardal et al., 2006	0,731	0,675	0,780	7,287	0,000	12,05
Bjelic Radisic et al., 2011	0,594	0,496	0,685	1,879	0,060	5,50
Deffieux et al., 2007	0,805	0,656	0,899	3,596	0,000	1,45
Glavind et al., 2012	0,733	0,467	0,896	1,733	0,083	0,66
Goktolga et al., 2008	0,574	0,431	0,706	1,017	0,309	2,60
Groutz et al., 2011	0,654	0,516	0,770	2,182	0,029	2,66
Han et al., 2014	0,795	0,698	0,867	5,139	0,000	3,24
Heidler et al., 2010	0,522	0,380	0,660	0,295	0,768	2,59
Kuuva & Nilsson, 2006	0,682	0,597	0,757	4,039	0,000	6,32
Lee et al., 2010	0,830	0,759	0,883	7,069	0,000	4,50
Li et al., 2012	0,745	0,615	0,843	3,471	0,001	2,36
Liapis et al. 2008	0,787	0,667	0,872	4,178	0,000	2,31
McCracken et al., 2007	0,833	0,657	0,929	3,285	0,001	0,94
Mohamad et al., 2013	0,527	0,426	0,626	0,518	0,604	5,24
Nilsson et al., 2013	0,873	0,756	0,938	4,759	0,000	1,38
Nwabineli et al., 2012	0,846	0,757	0,907	5,867	0,000	2,68
Olsson et al., 2010	0,766	0,684	0,832	5,593	0,000	5,02
Prien-Larsen & Hemmingsen, 2009	0,740	0,631	0,826	4,030	0,000	3,35
Reich et al., 2011	0,824	0,741	0,885	6,110	0,000	3,54
Serati et al., 2012	0,897	0,788	0,953	5,009	0,000	1,22
Svenningsen et al., 2013	0,761	0,720	0,797	10,716	0,000	19,42
Zugor et al., 2010	0,830	0,743	0,892	5,956	0,000	3,19
	0,727	0,709	0,745	20,646	0,000	



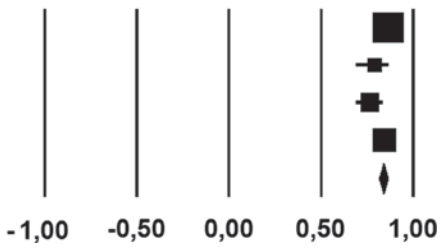
b

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value	Relative weight
Aigmueller et al., 2011	0,838	0,759	0,894	6,545	0,000	8,27
Ankardal et al., 2006	0,983	0,889	0,998	4,026	0,000	0,51
Bjelic Radisic et al., 2011	0,802	0,713	0,869	5,602	0,000	8,33
Goktolga et al., 2008	0,702	0,558	0,815	2,688	0,007	5,11
Heidler et al., 2010	0,783	0,641	0,879	3,583	0,000	4,07
Kuuva & Nilsson, 2006	0,786	0,706	0,849	5,984	0,000	11,02
Li et al., 2012	0,855	0,735	0,926	4,630	0,000	3,55
Liapis et al. 2008	0,803	0,685	0,885	4,368	0,000	5,01
Mohamad et al., 2013	0,656	0,554	0,745	2,956	0,003	10,90
Nilsson et al., 2013	0,913	0,790	0,967	4,494	0,000	1,90
Nwabineli et al., 2012	0,966	0,901	0,989	5,714	0,000	1,51
Olsson et al., 2010	0,837	0,753	0,896	6,157	0,000	7,39
Prien-Larsen & Hemmingsen, 2009	0,936	0,855	0,973	5,800	0,000	2,43
Reich et al., 2011	0,898	0,825	0,943	6,842	0,000	5,13
Serati et al., 2012	0,931	0,830	0,974	5,023	0,000	1,93
Svenningsen et al., 2013	0,899	0,861	0,928	11,729	0,000	14,95
Zugor et al., 2010	0,810	0,721	0,875	5,688	0,000	8,00
	0,832	0,812	0,851	22,219	0,000	



c

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Celibi et al. 2009	0,867	0,836	0,892	15,100	0,000
Chene et al., 2007	0,793	0,692	0,867	4,923	0,000
Doo et al., 2006	0,769	0,690	0,832	5,861	0,000
Song et al., 2009	0,846	0,802	0,883	10,764	0,000
	0,841	0,817	0,861	19,826	0,000



◀ **Fig. 4** Meta-analysis of the efficacy of retropubic TVT (non-RCTs). **a** Cumulative subjective cure rates; **b** Cumulative objective rates; **c** Composite cure rates

In RCTs vaginal erosions were less frequent with RP-MUS than with TO-MUS (OR 0.24, 95 % CI 0.07 – 0.84; p=0.03; Fig. 7a), while no differences were observed between TOT and TVT-O or between TO-MUS and minimally invasive slings (Fig. 7b, c). Neither pain (OR 0.78, 95 % CI 0.19 – 3.20) nor persistent voiding dysfunction (OR 1.23, 95 % CI 0.58 – 2.59) was significantly different between RP-MUS and TO-MUS (Fig. 7a–b). Similarly, no differences in these complications were observed between TOT and TVT-O (Fig. 7c).

Fig. 5 Meta-analysis of the efficacy of transobturator TVT (non-RCTs). **a** Cumulative subjective cure rates; **b** Cumulative objective rates

a

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Atahansiou et al., 2013	0,831	0,754	0,887	6,642	0,000
Canete et al., 2013 Mon	0,769	0,572	0,892	2,587	0,010
Canete et al., 2013 Obt	0,676	0,511	0,806	2,090	0,037
Cheng et al., 2012	0,900	0,824	0,945	6,592	0,000
Cheung et al., 2013 TVT-O	0,841	0,746	0,906	5,521	0,000
Cheung et al., 2013 Mon	0,817	0,731	0,880	5,904	0,000
Heinonen et al., 2013	0,835	0,763	0,888	7,089	0,000
Houwert TVT-O	0,720	0,608	0,810	3,672	0,000
Houwert Monarc	0,651	0,545	0,744	2,759	0,006
Liapis et al., 2010	0,791	0,707	0,856	5,808	0,000
Neuman et al., 2011	0,870	0,768	0,931	5,307	0,000
Rajendra et al., 2012	0,897	0,845	0,934	8,950	0,000
Serati et al., 2013	0,914	0,865	0,947	9,062	0,000
Waltregny et al., 2008	0,879	0,795	0,932	6,170	0,000
Zugor et al., 2010	0,787	0,700	0,854	5,561	0,000
	0,821	0,799	0,840	21.800	0,000

Statistics for each study

Event rate and 95% CI

-1,00 -0,50 0,00 0,50 1,00

b

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Atahansiou et al., 2013	0,831	0,754	0,887	6,642	0,000
Canete et al., 2013 Mon	0,769	0,572	0,892	2,587	0,010
Canete et al., 2013 Obt	0,676	0,511	0,806	2,090	0,037
Cheng et al., 2012	0,900	0,824	0,945	6,592	0,000
Cheung et al., 2013 TVT-O	0,841	0,746	0,906	5,521	0,000
Cheung et al., 2013 Mon	0,817	0,731	0,880	5,904	0,000
Heinonen et al., 2013	0,835	0,763	0,888	7,089	0,000
Houwert TVT-O	0,720	0,608	0,810	3,672	0,000
Houwert Monarc	0,651	0,545	0,744	2,759	0,006
Liapis et al., 2010	0,791	0,707	0,856	5,808	0,000
Rajendra et al., 2012	0,897	0,845	0,934	8,950	0,000
Serati et al., 2013	0,914	0,865	0,947	9,062	0,000
Waltregny et al., 2008	0,879	0,795	0,932	6,170	0,000
Zugor et al., 2010	0,787	0,700	0,854	5,561	0,000
	0,818	0,797	0,838	21,171	0,000

Statistics for each study

Event rate and 95% CI

-1,00 -0,50 0,00 0,50 1,00

c

Study name	Event rate	Lower limit	Upper limit	Z-Value	p-Value
Atahansiou et al., 2013	0,863	0,790	0,913	7,046	0,000
Cheung et al., 2013 TVT	0,951	0,877	0,982	5,794	0,000
Cheung et al., 2013 Mon	0,942	0,877	0,974	6,642	0,000
Liapis et al., 2010	0,887	0,815	0,933	6,995	0,000
Rajendra et al., 2012	0,997	0,959	1,000	4,178	0,000
Waltregny et al., 2008	0,967	0,903	0,989	5,755	0,000
Zugor et al., 2010	0,981	0,929	0,995	5,563	0,000
	0,917	0,890	0,937	15,360	0,000

Statistics for each study

Event rate and 95% CI

-1,00 -0,50 0,00 0,50 1,

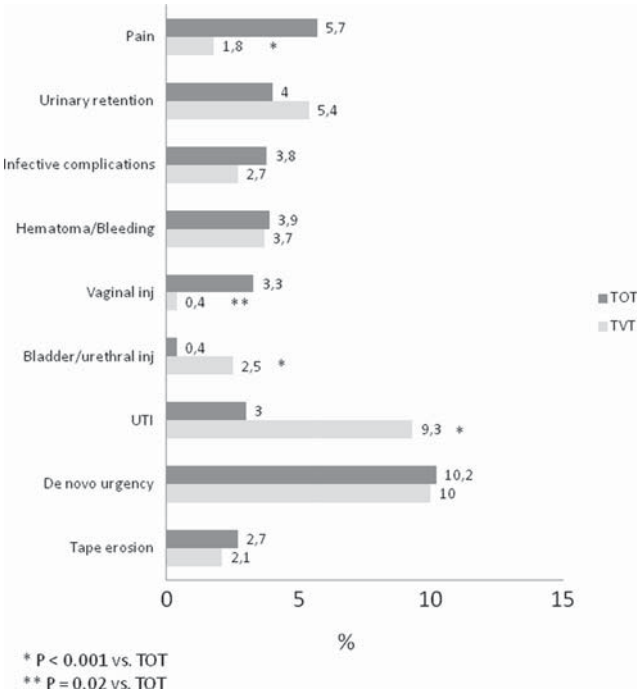


Fig. 6 Complications found in the studies evaluating long-term and medium-term outcomes following retropubic and transobturator TVT. *p<0.001 , **p=0.02, vs. transobturator TVT

Risk of bias

The risk of bias was assessed using a risk-of-bias graph (see Electronic supplementary material). Most RCTs had good sequence generation and allocation concealment; however, reporting of blinding methods in most RCTs was generally poor.

Heterogeneity

No studies were excluded on the basis of methodological heterogeneity. In RCTs, estimated statistical heterogeneity in complication rate (as measured by I^2) between RP-MUS and TO-MUS was moderate (between 25 % and 75 %) in the comparison. There was a high degree (>75 %) of statistical heterogeneity in subjective cure rate TOT and TVT-O. All other comparisons showed a low statistical heterogeneity (<25 %). In non-RCT studies, there was a high degree of statistical heterogeneity in efficacy outcomes for RP-MUS and moderate heterogeneity in efficacy outcomes for TO-MUS.

Discussion

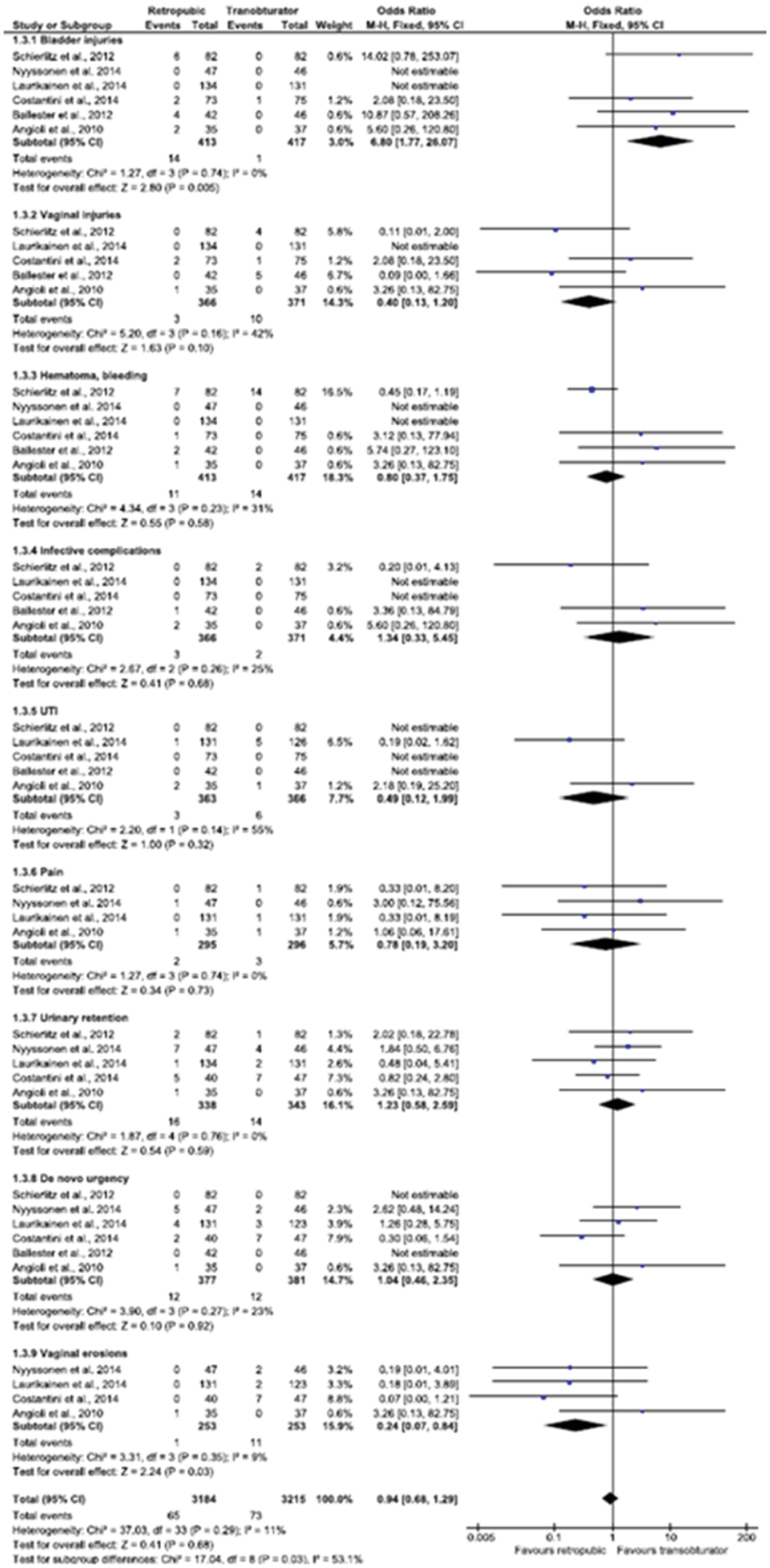
This meta-analysis indicated that both RP-MUS and TO-MUS are associated with high objective and subjective cure rates in the long- and medium-term. RCTs showed a significantly higher subjective cure rate with RP-MUS than with TO-MUS, due to one study defining subjective success as the absence of reoperation for recurrent SUI on request by the patients [21], which may have altered the results. On the other hand, equivalence of RP-MUS and TVT-O relies only on one study [18]. Our results are similar to those of Latthe et al. [3], Zhu et al. [8], and Schimpf et al. [11] for short term follow-up, but differ from those of Novara et al. [1] and Ogah et al. [5], who found a higher objective cure rate for retropubic TVT. However, on sensitive analysis, no differences were observed, so that a substantial similarity in the efficacy of these two approaches can be hypothesized, both in the short- and long-term. Non-RCT studies showed a somewhat lower subjective cure rate than objective cure rates for RP-MUS (72.7 % vs. 83.2 %). This outcome may be explained differently. Indeed, the tests used to objectively evaluate cure (mainly clinical stress test) may not reflect normal daily activities and thus underestimate the incidence of recurrent SUI. On the other hand, since in these studies women were followed up for a long time, a recall bias, including the onset of de novo urgency or urge incontinence unrelated to the original procedure, may have led to overestimation of the incidence of recurrent SUI by the patients. Finally, the heterogeneity in the tools used to subjectively evaluate patients across studies may also account for this outcome.

The number of RCTs comparing TVT-O and TOT in the medium-term are limited and objective cure rates were not reported in any of the studies. No differences were seen both in subjective cure rate and composite cure rates. This is in accordance with meta-analyses evaluating studies with shorter follow-up [4, 9], indicating that different transobturator tapes may yield similar results and that these results are maintained in the medium-term. There was no difference between objective and subjective cure rates of TO-MUS in non-RCT studies. This different finding compared with RP-MUS may reflect similar objective and subjective outcomes for transobturator tapes but may also be due either to the shorter follow-up period (lower recall bias) or to the fact that TO-MUS may be perceived as less invasive and dangerous.

No differences were observed between TO-MUS and new minimally invasive tapes. This last outcome is in accordance with a recent meta-analysis [6], which showed that traditional slings have similar efficacy when TVT SECUR is omitted from the analysis. However, other meta-analyses [11, 63] seem to indicate that single-incision slings have lower efficacy than traditional MUS. It is possible that, due to poor results, studies comparing single-incision slings and MUS were stopped earlier than after 36 months of follow-up, so that medium-term studies are those reporting good results for single-incision slings. Moreover, the data used for this meta-

Fig. 7 Meta-analysis of complications in RCTs. **a-b** Retropubic vs. transobturator TVT; **c** Inside-out vs. outside-in TVT; **d** Transobturator TVT vs. TFS, TVT SECUR, and TVT ABBREVO

a


Retropubic
Tranobturator
Odds Ratio
Odds Ratio
Study or Subgroup Events Total Events Total Weight M-H, Fixed, 95% CI
M-H, Fixed, 95% CI
1.3.1 Bladder injuries
Schierlitz et al., 2012 6 82 0 82 0.6% 14.02 [0.78, 253.07]
Nyyssonen et al. 2014 0 47 0 46 Not estimable
Laurikainen et al., 2014 0 134 0 131 Not estimable
Costantini et al., 2014 2 73 1 75 1.2% 2.08 [0.18, 23.50]
Ballester et al., 2012 4 42 0 46 0.6% 10.87 [0.57, 208.26]
Angioli et al., 2010 2 35 0 37 0.6% 5.60 [0.26, 120.80]
Subtotal (95% CI) 413 417 3.0% 6.80 [1.77, 26.07]
Total events 14 1
Heterogeneity: Chi² = 1.27, df = 3 (P = 0.74); I² = 0%
Test for overall effect: Z = 2.80 (P = 0.005)
1.3.2 Vaginal injuries
Schierlitz et al., 2012 0 82 4 82 5.8% 0.11 [0.01, 2.00]
Laurikainen et al., 2014 0 134 0 131 Not estimable
Costantini et al., 2014 2 73 1 75 1.2% 2.08 [0.18, 23.50]
Ballester et al., 2012 0 42 5 46 6.7% 0.09 [0.00, 1.66]
Angioli et al., 2010 1 35 0 37 0.6% 3.26 [0.13, 82.75]
Subtotal (95% CI) 366 371 14.3% 0.40 [0.13, 1.20]
Total events 3 10
Heterogeneity: Chi² = 5.20, df = 3 (P = 0.16); I² = 42%
Test for overall effect: Z = 1.63 (P = 0.10)
1.3.3 Hematoma, bleeding
Schierlitz et al., 2012 7 82 14 82 16.5% 0.45 [0.17, 1.19]
Nyyssonen et al. 2014 0 47 0 46 Not estimable
Laurikainen et al., 2014 0 134 0 131 Not estimable
Costantini et al., 2014 1 73 0 75 0.6% 3.12 [0.13, 77.94]
Ballester et al., 2012 2 42 0 46 0.6% 5.74 [0.27, 123.10]
Angioli et al., 2010 1 35 0 37 0.6% 3.26 [0.13, 82.75]
Subtotal (95% CI) 413 417 18.3% 0.80 [0.37, 1.75]
Total events 11 14
Heterogeneity: Chi² = 4.34, df = 3 (P = 0.23); I² = 31%
Test for overall effect: Z = 0.55 (P = 0.58)
1.3.4 Infective complications
Schierlitz et al., 2012 0 82 2 82 3.2% 0.20 [0.01, 4.13]
Laurikainen et al., 2014 0 134 0 131 Not estimable
Costantini et al., 2014 0 73 0 75 Not estimable
Ballester et al., 2012 1 42 0 46 0.6% 3.36 [0.13, 84.79]
Angioli et al., 2010 2 35 0 37 0.6% 5.60 [0.26, 120.80]
Subtotal (95% CI) 366 371 4.4% 1.34 [0.33, 5.45]
Total events 3 2
Heterogeneity: Chi² = 2.67, df = 2 (P = 0.26); I² = 25%
Test for overall effect: Z = 0.41 (P = 0.68)
1.3.5 UTI
Schierlitz et al., 2012 0 82 0 82 Not estimable
Laurikainen et al., 2014 1 131 5 126 6.5% 0.19 [0.02, 1.62]
Costantini et al., 2014 0 73 0 75 Not estimable
Ballester et al., 2012 0 42 0 46 Not estimable
Angioli et al., 2010 2 35 1 37 1.2% 2.18 [0.19, 25.20]
Subtotal (95% CI) 363 366 7.7% 0.49 [0.12, 1.99]
Total events 3 6
Heterogeneity: Chi² = 2.20, df = 1 (P = 0.14); I² = 55%
Test for overall effect: Z = 1.00 (P = 0.32)
1.3.6 Pain
Schierlitz et al., 2012 0 82 1 82 1.9% 0.33 [0.01, 8.20]
Nyyssonen et al. 2014 1 47 0 46 0.6% 3.00 [0.12, 75.56]
Laurikainen et al., 2014 0 131 1 131 1.9% 0.33 [0.01, 8.19]
Angioli et al., 2010 1 35 1 37 1.2% 1.06 [0.06, 17.61]
Subtotal (95% CI) 295 296 5.7% 0.78 [0.19, 3.20]
Total events 2 3
Heterogeneity: Chi² = 1.27, df = 3 (P = 0.74); I² = 0%
Test for overall effect: Z = 0.34 (P = 0.73)
1.3.7 Urinary retention
Schierlitz et al., 2012 2 82 1 82 1.3% 2.02 [0.18, 22.78]
Nyyssonen et al. 2014 7 47 4 46 4.4% 1.84 [0.50, 6.76]
Laurikainen et al., 2014 1 134 2 131 2.6% 0.48 [0.04, 5.41]
Costantini et al., 2014 5 40 7 47 7.3% 0.82 [0.24, 2.80]
Angioli et al., 2010 1 35 0 37 0.6% 3.26 [0.13, 82.75]
Subtotal (95% CI) 338 343 16.1% 1.23 [0.58, 2.59]
Total events 16 14
Heterogeneity: Chi² = 1.87, df = 4 (P = 0.76); I² = 0%
Test for overall effect: Z = 0.54 (P = 0.59)
1.3.8 De novo urgency
Schierlitz et al., 2012 0 82 0 82 Not estimable
Nyyssonen et al. 2014 5 47 2 46 2.3% 2.62 [0.48, 14.24]
Laurikainen et al., 2014 4 131 3 123 3.9% 1.26 [0.28, 5.75]
Costantini et al., 2014 2 40 7 47 7.9% 0.30 [0.06, 1.54]
Ballester et al., 2012 0 42 0 46 Not estimable
Angioli et al., 2010 1 35 0 37 0.6% 3.26 [0.13, 82.75]
Subtotal (95% CI) 377 381 14.7% 1.04 [0.46, 2.35]
Total events 12 12
Heterogeneity: Chi² = 3.90, df = 3 (P = 0.27); I² = 23%
Test for overall effect: Z = 0.10 (P = 0.92)
1.3.9 Vaginal erosions
Nyyssonen et al. 2014 0 47 2 46 3.2% 0.19 [0.01, 4.01]
Laurikainen et al., 2014 0 131 2 123 3.3% 0.18 [0.01, 3.89]
Costantini et al., 2014 0 40 7 47 8.8% 0.07 [0.00, 1.21]
Angioli et al., 2010 1 35 0 37 0.6% 3.26 [0.13, 82.75]
Subtotal (95% CI) 253 253 15.9% 0.24 [0.07, 0.84]
Total events 1 11
Heterogeneity: Chi² = 3.31, df = 3 (P = 0.35); I² = 9%
Test for overall effect: Z = 2.24 (P = 0.03)
Total (95% CI) 3184 3215 100.0% 0.94 [0.68, 1.29]
Total events 65 73
Heterogeneity: Chi² = 37.03, df = 33 (P = 0.29); I² = 11%
Test for overall effect: Z = 0.41 (P = 0.68)
Test for subgroup differences: Chi² = 17.04, df = 8 (P = 0.03), I² = 53.1%
0.005 0.1 1 10 200
Favours retropubic Favours transobturator

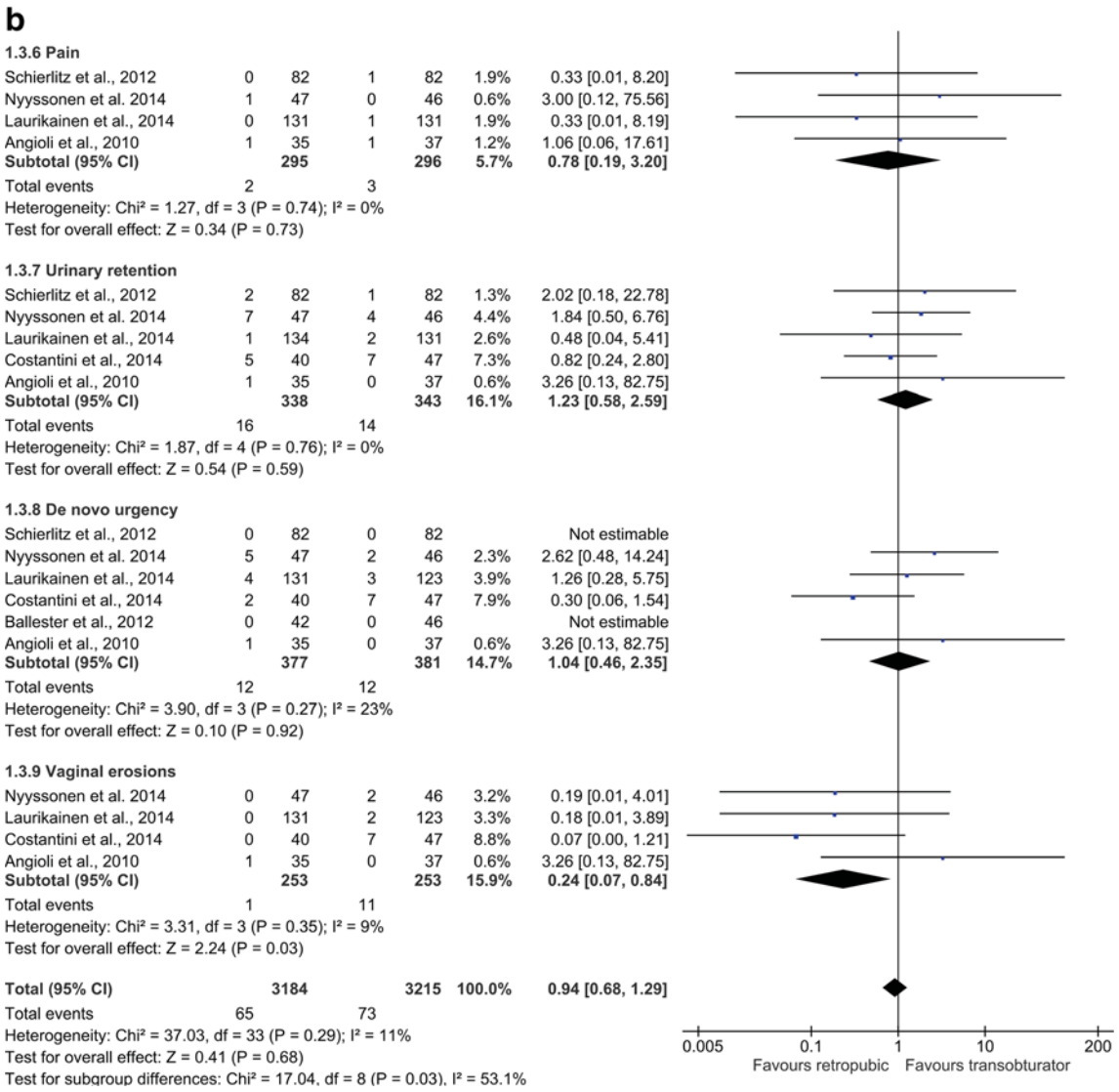


Fig. 7 (continued)

analysis are too limited to draw any conclusion and a modified transobturator tape was arbitrarily included in the group of minimally invasive slings (TVT ABBREVO) for its low invasiveness. The two approaches also proved to be relatively safe, with only a limited number of serious complications. The most frequent complication was de novo OAB symptoms for both approaches which, although possibly disturbing, can be treated either with tape division or anticholinergic drugs. The second most frequent complication with TO-MUS was pain, with an incidence of 6 %. All reported episodes, i.e. postoperative, persistent and chronic pain, are included in this analysis and most were postoperative or persistent pain that resolved within weeks or months, with no long-term sequelae. The rate of chronic pain in the groin and/or the thigh is far lower. It must be underlined that not all studies clearly defined postoperative, persistent and chronic pain, so that it was difficult to correctly identify the cases that remained unresolved.

RP-MUS showed a higher rate of bladder perforations, in accordance with the findings of other meta-analyses [1, 3, 5, 8]. The higher incidence of vaginal extrusion with TO-MUS than with RP-MUS was not found in those studies evaluating short-term follow-up. A possible explanation may be that, in the medium-term, RP-MUS are more at risk of developing a vaginal extrusion than RP-MUS. Interestingly, pain did not differ between the two groups, contrary to the findings of other meta-analyses [4, 8]. This finding may be due to the fact that in a number of studies only on chronic pain was reported, which may not be different between the two devices.

As reported by others [9], TVT-O was associated with a significantly lower incidence of vaginal injuries than TOT, but other complications did not differ between the two approaches. There was a trend toward lower vaginal extrusion

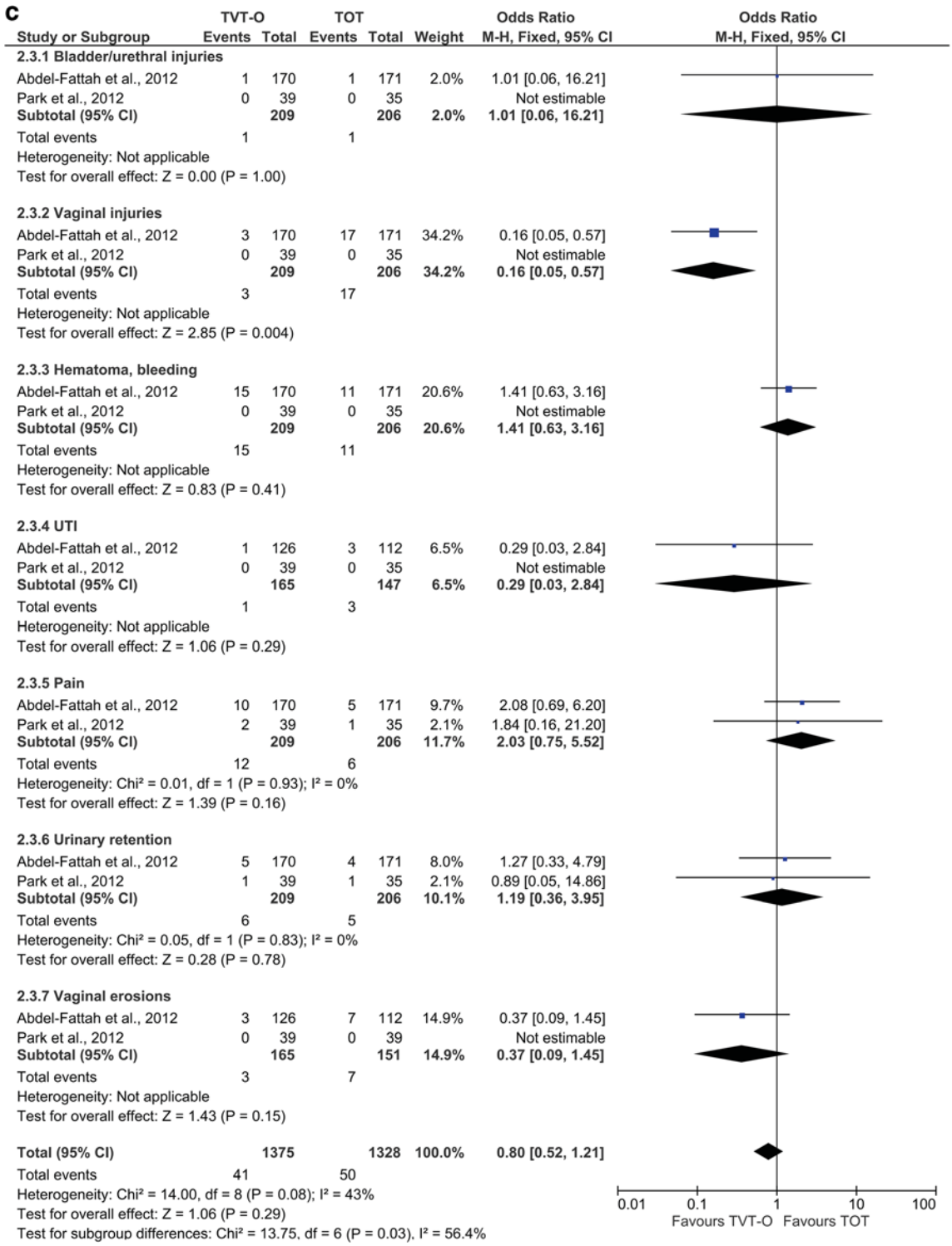


Fig. 7 (continued)

with TVT-O (OR 0.37), not reaching statistical significance. Overall, these results seem to indicate that both TOT approaches yield similar medium-term safety outcomes.

To our knowledge, only one meta-analysis evaluating long-term outcomes of MUS has been done [10], but the authors included studies with a minimum follow-up of 12 months. As suggested by Hilton [12], medical

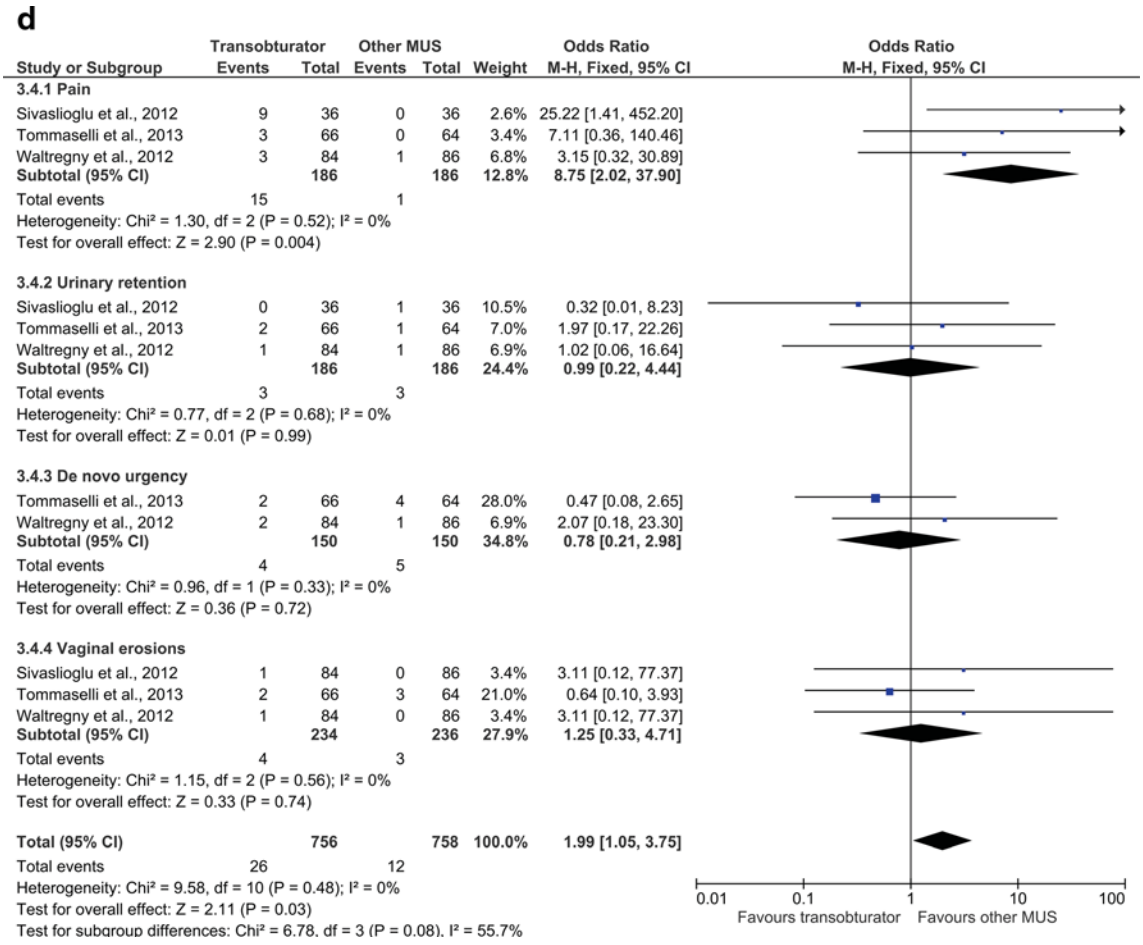


Fig. 7 (continued)

devices cannot be compared to drugs, so that a follow-up of 12 months cannot be regarded as long-term. Considering that synthetic material is left in the body of the patient, with continuous interplay with the patient's own tissues, for a study to be considered long-term, it should have a follow-up of at least 5 years. Tan et al. [10] found similar objective and subjective cure rates between RP-MUS and TVT-O, thus suggesting that these outcomes are either maintained over the years or that the efficacy of these devices decreases similarly.

The limitations of this analysis were the exclusion of congress abstracts, the inclusion of unselected patients and the inclusion of nonrandomized trials. Congress abstracts often reports preliminary studies that are subsequently published as peer-reviewed articles, so that very little information is lost by excluding these data. The inclusion of an unselected population (patients with mixed urinary incontinence, and patients with intrinsic sphincter deficiency), as well as the inclusion of nonrandomized, prospective and retrospective studies, are representative of situations we normally observe during everyday practice. It is almost impossible to reproduce the scientific setting in which randomized trials are implemented in our offices and operating rooms, and RCTs do not always reproduce "real-life" situations.

In conclusion, this meta-analysis showed that RP-MUS and TO-MUS have similar objective cure rates in the long-term and medium-term but TOTs have a lower subjective cure rate than TVT. This efficacy is backed by a high safety profile, and by a limited number of complications which were seldom severe. More randomized trials comparing TVT-O and TOT investigating objective cure rates and with a longer follow-up are needed, and further data are needed regarding minimally invasive slings to be able to draw more accurate conclusions.

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Conflicts of interest G.A. Tommaselli is consultant for Ethicon, Inc. and Solace Therapeutics, Inc.

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